ESTIMATION OF LEAD BIOAVAILABILITY IN SOIL AND DUST: UPDATE TO THE DEFAULT VALUES FOR THE INTEGRATED EXPOSURE UPTAKE BIOKINETIC MODEL FOR LEAD IN CHILDREN

OVERVIEW

Since 1994, the Office of Solid Waste and Emergency Response (OSWER) has recommended the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK model) as a risk assessment tool to support environmental cleanup decisions at residential sites (U.S. EPA, 1994a, b). The IEUBK model uses empirical data from numerous scientific studies of lead uptake and biokinetics, contact and intake rates of children with contaminated media, and data on the presence and behavior of environmental lead to predict a plausible distribution or geometric mean (GM) of blood lead (PbB) for a hypothetical child or population of children[1]. The relative variability of PbB concentrations around the GM is defined as the geometric standard deviation (GSD). The GSD encompasses biological and behavioral differences, measurement variability from repeat sampling, variability as a result of sample locations, and analytical variability[2]. From this distribution, the IEUBK model estimates the risk (*i.e.*, probability) that a child's or a population of children's PbB concentration will exceed a certain level of concern as currently established at [redacted] micrograms per deciliter (µg/dL) (U.S. EPA, 1994a, 1998, White et al., 1998).

The background default value for the *Absorption Fraction*, or absolute bioavailability (ABA), for lead in soil and indoor dust in the IEUBK model is [redacted] or [redacted]%. This value corresponds to a relative bioavailability (RBA) of [redacted] or [redacted]% (relative to water soluble lead). The default values were originally derived from an absorption algorithm based on data from lead mass balance and feeding studies in human infants and children (U.S. EPA 1994a).

When reliable data are available on the bioavailability of lead in soil, dust, or other soil-like waste material at a site, this information can be used to improve the accuracy of exposure and risk calculations at that site. In application for risk assessment, bioavailability adjustments are generally applied to the concentration term. Consequently, information related to the bioavailability of a contaminant in the exposure medium may be as important as the

[1]The GM represents the central tendency estimate (e.g., mean, [redacted] percentile) of PbB concentration of children from a hypothetical population (Hogan et al., 1998). The TRW recommends that the soil contribution to dust lead be evaluated by comparing the average or arithmetic mean of soil lead concentrations from a representative area in the child's yard (U.S. EPA, 1994a). If an arithmetic mean (or average) is used, the model provides a central point estimate for risk of an elevated PbB level. By definition, a central tendency estimate is equally likely to over- or under-estimate the soil/indoor dust RBA at lead-contaminated sites. Upper confidence limits (UCLs) can be used in the IEUBK model; however, the IEUBK model results could be interpreted as a more conservative estimate of the risk of an elevated PbB level. See U.S. EPA (1994b) for further information.

[2]The IEUBK model uses a log-normal probability distribution to characterize this variability (U.S. EPA, 1994a). The biokinetic component of the IEUBK model output provides a central estimate of PbB concentration, which is used to provide the geometric standard deviation (GSD). The GSD encompasses biological and behavioral differences, measurement variability from repeat sampling, variability as a result of sample locations, and analytical variability. In the IEUBK model, the GSD is intended to reflect variability in PbB concentrations where different individuals are exposed to different media concentrations of lead. The recommended default value for GSD ([redacted]) was derived from empirical studies with young children where both blood and environmental lead concentrations were measured (White et al., 1998).

concentration of the contaminant in that medium (although bioavailability, generally expressed as a percent, will not generally vary as much as concentration).

[redacted]

Table 1. Comparison of current and proposed estimates for the Absorption Fraction variable in the IEUBK model.

	Absorption Fraction	
Parameter	**Previous IEUBK Model CTE Default[a]**	**Proposed RME IEUBK Model Default[b]**
Soil	[redacted]	[redacted]
Dust	[redacted]	[redacted]

[a]Central tendency estimates
[b]The Reasonable Maximum Exposure (RME) is based on an upper percentile estimate

This document provides the technical basis for updating the *Absorption Fraction* variable in the IEUBK model. The intended audience is risk assessors familiar with using the IEUBK model. For further background information on both this variable and use of the IEUBK model in Superfund lead risk assessment, refer to U.S. EPA (1994a) or the Technical Review Workgroup for Lead (TRW) website (http://epa.gov/superfund/lead/trw.htm).

<u>INTRODUCTION</u>

The IEUBK model predicts PbB concentrations in young children exposed to lead from several sources and routes. The IEUBK model uses more than [redacted] input parameters that are initially set to default values. Of these, there are [redacted] parameters that may be input, or modified, by the user; the remainder are locked (U.S. EPA, 1994a). Default values represent national averages or other central tendency values derived from a) empirical data in the open literature, which include lead concentrations in exposure media including a diet representative of national food sources, b) contact and intake rates, such as the soil/dust ingestion, and c) exposure durations (White et al., 1998). The representativeness of IEUBK model output is dependent on the representativeness of the data (often assessed in terms of: completeness, comparability, precision, and accuracy [U.S. EPA, 1994a]).

Representative site-specific data are essential for developing a risk assessment (as well as cleanup goals) that reflect the current or potential future conditions. The most common type of site-specific data is media-specific lead concentration information (air, water, soil, dust). Until recently, an inexpensive, validated method to estimate bioavailability of lead in soil or dust was not available. Receptor data (*e.g.*, age, body weight, breathing rate, or soil ingestion rate) does not typically vary from site to site.

OSWER recognizes that the minimum data required for site-specific risk assessment can support site decisions; however, supplemental community-specific information can be useful in supporting risk management decisions. In general, the information to support a risk assessment can be characterized as either site-specific *environmental media data* or community-specific *socioeconomic and receptor data.*

The following are site-specific exposure point concentrations:

- Soil lead concentration[3]
- Soil Bioavailability information (IVBA analysis)
- Dust lead concentration[3]
- Dust Bioavailability information (IVBA analysis)
- Water lead concentration
- Air lead concentration
- Alternate dietary lead intake (*e.g.*, garden produce, hunted game, fish from fishing)

To promote defensible and reproducible risk assessments and cleanup plans, while maintaining flexibility needed to respond to different site conditions, U.S. EPA recommends the Data Quality Objectives process (U.S. EPA, 2006). Data Quality Objectives provide a structured approach to collecting environmental data that will be sufficient to support decision-making (http://www.epa.gov/QUALITY/dqos.html).

Depending on the chemical and physical characteristics of lead, less than [redacted]% of lead entering the body is readily absorbed into systemic circulation (*i.e.*, bioavailability). The term bioavailability can be expressed either in absolute terms (absolute bioavailability) or in relative terms (relative bioavailability). U.S. EPA (2007a) defines absolute bioavailability (ABA) as the ratio of the amount of the chemical absorbed to the amount ingested (*i.e.*, ABA = Absorbed Dose/Ingested Dose). Relative bioavailability is indexed by measuring the bioavailability of a particular substance relative to a standard reference material, such as lead acetate (*i.e.*, RBA = $ABA_{\text{test material}}/ABA_{\text{reference material}}$) (U.S. EPA, 1994a). For example, if [redacted] micrograms (μg) of lead dissolved in drinking water were ingested and a total of [redacted] μg of lead were absorbed into the

[3] These data elements are the minimal required data for site-specific risk assessment (U.S. EPA, 1994a).

body, the ABA would be [redacted] ([redacted]%). Likewise, if [redacted] μg of lead in soil were ingested and [redacted] μg were absorbed into the body, the ABA for soil would be [redacted] ([redacted]%) (U.S. EPA, 2007a).

In the IEUBK model, bioavailability , which is referred to as the *Absorption Fraction*, represents a central tendency estimate for lead that is absorbed in a child's gastrointestinal tract into the systemic circulation of blood. Soluble lead in water and food is estimated to have an ABA of [redacted] ([redacted]%) based on the bioavailability of soluble lead acetate (*i.e.*, the standard reference material). Lead in soil and dust, however, are estimated to have an ABA of [redacted] ([redacted]%). This value corresponds to an RBA of [redacted] ([redacted]%; *i.e.*, RBA=$ABA_{\text{soil or dust}}/ABA_{\text{soluble lead acetate}}$ = [redacted]/[redacted]). These values were designed to provide representative estimates of lead absorption in children in the U.S. but are not intended to replace representative site-specific data. U.S. EPA (2007a) provides examples of the variability of soil lead RBA for a variety of sites in the United States. The TRW Lead Committee recognizes that bioavailability of lead in soil is influenced by a variety of factors and that there are limitations in both the *in vivo* and *in vitro* assays (U.S. EPA 2007b). Nevertheless, utilization of *in vivo* (juvenile swine) assays (*i.e.*, bioavailability) and more cost-efficient *in vitro* assays (*i.e.*, bioaccessibility; IVBA) to provide site-specific estimates of RBA reduces uncertainty in estimates of potential human health risk at a site[4].

In Vivo Method (Swine Assay)

The TRW Lead Committee identified twenty reports with information on bioavailability of lead in soil and "soil-like" materials in juvenile swine (Bannon et al., 2009; Casteel et al., 1996a-d; 1997a,b; 1998a-d; 2001; 2004; 2006a-c; Juhasz et al., 2009; Marschner et al., 2006; Smith et al., 2009). Collectively, these studies conducted in swine include [redacted] estimates of lead RBA for [redacted] different soil or "soil-like" test materials (Table 2, two RBA estimates are available for the material identified as *Palmerton 2*).

Bannon et al. (2009) measured RBA of lead in eight soil samples from small arms firing ranges in the U.S. The soil samples were sieved to ≤250 μm, and soil lead concentration ranged from [redacted] mg/kg to [redacted] mg/kg. As described by Bannon et al. (2009), the lead values used for dosing animals ranged from [redacted] mg/kg to [redacted] mg/kg (Table 2). The soil samples were thoroughly characterized with regard to lead mineral phase, particle size distribution, and lead matrix association using electron microprobe analysis.

Casteel et al. (1996a-d; 1997a,b; 1998a-d; 2001; 2004; 2006a-c) measured RBA of lead in [redacted] soil and soil-like materials from the U.S. The soil samples included discrete and composite samples from a number of Superfund sites, as well as two soil samples spiked with galena or National Institute for Standards and Technology (NIST) Standard Reference Material (SRM) lead paint. Test materials were sieved to [redacted] μm, and the lead concentrations ranged from [redacted] mg/kg to [redacted] mg/kg (Table 2). The soil samples were thoroughly characterized with regard to lead mineral phase, particle size distribution, and lead matrix association using electron microprobe analysis. Because the intent of this analysis was to focus on materials that would be

[4] Each system is based on the concept of rate and/or extent of lead solubility in gastrointestinal (*in vivo*) or similar gastric fluid (IVBA) (U.S. EPA, 2007a).

representative of soil at Superfund sites, the galena-enriched soil and NIST SRM paint samples were excluded from the analysis.

Juhasz et al. (2009) measured RBA of lead in five soil samples from two sites: an urban residential land site and a former domestic incinerator in Australia. Samples were sieved to [redacted] µm, and soil lead concentrations ranged from [redacted] mg/kg to [redacted] mg/kg (Table 2). Soil samples were characterized for pH, organic carbon, and concentrations of phosphorous, iron, aluminum, and lead. Although the soil samples in this study are from outside the U.S., the samples are included in the analysis because they represent various sources of urban soil lead contamination not represented in other data sets (*e.g.*, domestic incinerator). In addition, there is no reason to believe these sources of lead would be appreciably different from similar sources in the U.S.

Marschner et al. (2006) measured RBA of lead in five soil samples from Germany. Soil samples were sieved to ≤1 mm, and lead concentrations ranged from [redacted] mg/kg to [redacted] mg/kg. Soil samples were characterized for clay (%), pH, organic carbon, and concentrations of arsenic, cadmium, lead, chromium, and nickel. Lead doses ranged from [redacted] mg/animal to [redacted] mg/animal [redacted] to [redacted] µg/kg-bw, respectively; Table 2). However, this study was excluded from the analysis of soil RBA due to the sieving size of this study differing from the other juvenile swine studies. Also, the particle size [redacted] mm) is known to affect bioavailability of soil.

Smith et al. (2009) measured RBA of lead in two soil samples from Tacoma, Washington. The lead in the soil samples was presumed to come from smelter emissions. Soil samples were sieved to [redacted] µm, and the lead concentration of each sample was [redacted] mg/kg (Table 2). Soil samples were characterized for clay (%), pH, organic carbon, CO_2, and lead concentration.

In Vitro Method (IVBA)

A review of soil lead RBA estimates made using the IVBA assay and the equation listed above identified [redacted] estimates of lead RBA in soils obtained from [redacted] hazardous waste sites in U.S. EPA Regions 7 and 8 (U.S. EPA, 2007a). In addition, a review of indoor dust lead RBA estimates made using the IVBA assay identified [redacted] estimates of lead RBA in dusts obtained from the Herculaneum and Omaha Superfund sites. Small arms firing ranges that utilized the IVBA method to assess bioaccessibility of lead in the firing range soil was also reviewed (Bannon et al., 2009).

Results

Of the [redacted] sites (excluding firing ranges), the estimates include [redacted] based on swine bioassays and [redacted] based on IVBA assays. Distributions of RBAs for various relevant strata of the data set described in this memorandum are shown in Table 3. The sample of estimates for soils based on the combined data from IVBA assays (site means) and *in vivo* swine assays (excluding firing ranges and soils sieved to include particle sizes [redacted] µm) has a median of [redacted]% and a [redacted] – [redacted] percentile range of [redacted] – [redacted] (n= [redacted] soil samples, [redacted] sites; Table 3). Excluding firing ranges where lead may have RBA values of [redacted]%, soil lead RBA can be expected to have values that fall within the [redacted] – [redacted] percentile range.

IN VIVO METHOD (SWINE ASSAY)

Tables 3 and 4 present the summary statistics for all test materials (total of [redacted] different test materials, collected from [redacted] different sites). Analysis of [redacted] soils (excluding galena-enriched soil, the NIST SRM paint sample, soils from firing ranges, and soils sieved at [redacted] mm reported in Marschner et al., 2006) resulted in a median RBA estimate of [redacted]% with the [redacted] percentile range from [redacted]% (Table 3); the mean RBA is [redacted]% (SD [redacted];Table 4). RBA estimates for soils collected from [redacted] firing ranges were approximately [redacted]% (mean = [redacted]%, SD [redacted]; Bannon et al., 2009). The relatively high RBA for the firing range soils may reflect the high abundance of relatively un-encapsulated lead carbonate ([redacted]% abundance) and lead oxide ([redacted]%) in these soils. Similarly, a soil sample (low lead concentration) mixed with a NIST paint standard ([redacted]% lead carbonate, [redacted]% lead oxide) also had a relatively high bioavailability ([redacted]%, Casteel et al., 2006a). Samples of smelter slag, or soils contaminated with slag, had relatively low RBA ([redacted]%, n=[redacted] as did a sample from a mine tailings pile (RBA=[redacted]%), and a sample of finely ground galena mixed with soil ([redacted]%; Casteel et al., 2006a). A single estimate for RBA of interior dust was [redacted]% for a sample collected at the Herculaneum site (Casteel et al., 2006c). Table 2 presents the RBA estimate and descriptive data for each test material, and summary statistics for RBA estimates are provided in Tables 3 and 4. Distributions of RBAs are shown in Figure 2.

IN VITRO METHOD (IVBA)

Summary statistics for estimated RBAs based on the IVBA assay are presented in Table 3 and Tables 5 to 8. Tables 3 and 5 present the summary statistics of RBA estimates for [redacted] test materials collected at [redacted] different sites. In Table 6, the individual test material estimates have been aggregated by site, and summary statistics for the site mean RBAs are presented. Table 7 presents the statistics for the RBA estimates at each site. The median for the site-wide RBA estimates based on IVBA assays was [redacted]%, and the [redacted] percentile range was [redacted]% (n=[redacted] soil samples, [redacted] sites; Table 3); the mean RBA is [redacted]% (SD [redacted] Table 6). The resulting range of RBA estimates is significantly less than the range of *in vivo* RBA values reported above, which is likely due to the fact that the IVBA assays were all performed on soils from U.S. EPA Regions 7 and 8.

Summary statistics for RBA estimates of interior dust test materials (and soil) are presented in Table 5, and the distribution of soil and dust test material RBA values is shown in Figure 3. A comparison of estimated RBAs for soil and interior dust test materials from two sites is presented in Table 8. Mean lead RBA estimates for the Herculaneum site were [redacted]% (SD [redacted], n=[redacted] samples) for indoor dust and [redacted]% (SD [redacted] n=[redacted] samples) for soil. At the Omaha Superfund site, mean lead RBA estimates were [redacted]% (SD [redacted], n=[redacted] samples) for indoor dust and [redacted]% (SD [redacted], n=[redacted] samples) for soil.

UNCERTAINTY

Limitations in these data preclude making statistical inference about lead RBA in U.S. soils or predicting lead RBA at any specific site. The RBA estimates evaluated were derived from an opportunistic sample of soils and dusts collected at sites where there was a regulatory interest (*e.g.*, remedial investigation or risk assessment) and sufficient resources for analysis (for sites where *in vivo* data are available). Although the data set includes samples from sites impacted by various sources of lead contamination (*e.g.*, mining/smelting, incinerator, shooting ranges), the dominant lead sources in the data set are mining and smelting. As a consequence, the soil and dust samples are not a statistical sample of soils in any geographic region in the U.S. or source of lead contamination, and extrapolation of these parameters to U.S. soils in general or to a soil at a specific site would be highly uncertain. Nevertheless, the data set has unique value for describing the distribution of lead RBA values that have been encountered in soils from various sites of regulatory interest.

The sample of RBAs shows large variability, both across sites and within sites. The [redacted]–[redacted] percentile range for all soils (excluding firing ranges) is [redacted]% – [redacted]% for combined IVBA and juvenile swine assays. A wide range of variability within sites is also evident. Within site coefficients of variation (SD/mean) range from [redacted]% to [redacted]% of the mean based on IVBA results. This suggests that, at some sites, adequate assessment of a representative value for site-wide soil lead RBA would require sampling at many different locations to ascertain variability. Sources contributing to the variability in these data have not been fully explained, although the relatively strong relationship between IVBA and *in vivo* RBA (*i.e.*, R^2 [redacted]) suggests that factors that govern bioaccessibility (*e.g.*, solubility at stomach pH) are important determinants of RBA (Casteel et al., 2006a; U.S. EPA, 2007a). Therefore, some of the variability observed may reflect variability in factors that determine lead solubility (*e.g.*, lead mineralogy, soil characteristics, physical characteristics of lead particles), which may be dependent on the source of lead and its history in the soils.

The swine assay has not been evaluated against data in children, and the primary rationale for using the assay is based on similar physiology (U.S. EPA, 2007a). This data set includes RBA estimates derived from several different swine bioassay protocols (*e.g.*, single dose, multiple dose) and comparisons of results from each protocol when applied to the same test materials are not available. Some soil materials assayed were sieved to include relatively large particle sizes (*i.e.*, [redacted] mm, Marschner et al., 2006) that may not represent particles that would be expected to adhere to skin ([redacted] µm) and, therefore, be relevant to risk assessment (Kissel et al., 1996; Choate et al., 2006). For this reason, summary statistics are presented in this memorandum with and without the Marschner et al. (2006) data.

The regression equation relating RBA and IVBA used in this analysis (Drexler and Brattin, 2007) is not applicable to other *in vitro* assays that have been developed for estimating lead IVBA and should not be used to estimate RBA from these *in vitro* assays without validation against *in vivo* RBA measurements made on the same test materials.

Comparisons of *in vitro* assays applied to the same soil test materials have also found considerable variability in IVBA estimates (Saikat et al., 2007; Van de Wiele et al., 2007). This variability has been attributed to differences in assay conditions, including pH, liquid:soil ratios, inclusion or absence of food material, and differences in methods used to separate dissolved and particulate lead (*e.g.*, centrifugation vs. filtration). Given the dependence of IVBA results on assay conditions, *in vitro* assays used to predict *in vivo* RBA should be further evaluated against *in vivo* RBA estimates to quantify uncertainty in RBA predictions for sites that differ from those in the validation (U.S. EPA, 2007a). Furthermore, the IVBA assay used in studies of interior dust has not been evaluated against *in vivo* RBA estimates for dust samples. Although, it is expected that a validated IVBA methodology for soil would perform well for predicting RBA of interior dust, this has not been experimentally confirmed. Factors that may affect *in vitro* predictions of RBA of interior dust lead could include particle size distribution of interior dust lead and the composition of the dust matrix, which may be quite different from that of soil.

The use of the IVBA assay for predicting *in vivo* RBA of soils that have been treated with high levels of phosphate (*e.g.*, [redacted]% phosphoric acid w/w) is not recommended. A comparison of *in vitro* bioaccessibility and *in vivo* RBA of lead in soils that were treated or not treated with phosphate ([redacted] or [redacted]% phosphoric acid w/w) showed that while phosphate treatment decreased *in vitro* bioaccessibility, it had no significant effect on *in vivo* RBA measured in swine (U.S. EPA, 2004). X-ray diffraction (XRD) studies of lead mineralogy of soils indicate that treatment of soil with phosphate will promote the formation of insoluble pyromorphite which, in theory, would be expected to decrease lead bioavailability (Scheckel and Ryan, 2004). However, *in vitro* extraction assays also perturb the *in situ* equilibrium between lead pyromorphite and more soluble lead species, and some *in vitro* assays actually promote the formation of insoluble pyromorphite (Scheckel at al., 2005). The *in vitro* formation of pyromorphite could result in an underestimate of *in situ* bioaccessibility and *in vivo* RBA. TRW will provide recommendations related to phosphate amendments in the future.

RECOMMENDATIONS FOR THE IEUBK MODEL

[redacted]

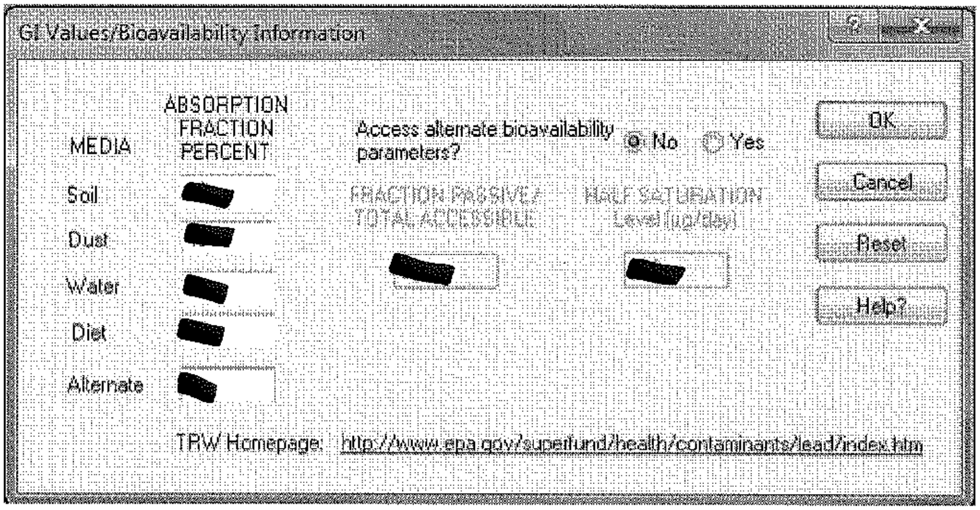

Figure 1. Proposed IEUBK model default values for the soil and dust absorption fractions.

The TRW recommends that all lead-contaminated Superfund Sites include representative site-specific bioavailability using the validated IVBA test for estimating soil lead RBA at the site (U.S. EPA, 2008)[5]. The TRW also recommends that a central tendency estimate from representative site-specific IVBA analyses be used as the input to the IEUBK model for all decision units within a site. Using a central tendency estimate for calculation of risk or a soil cleanup goal is consistent with using central tendency values as inputs to the IEUBK model (White et al., 1998).

IMPACT ON IEUBK MODEL PREDICTIONS

The empirical distribution of RBA values in this data set suggests that values for soil and dust lead RBA exceeding [redacted]% are relatively uncommon (*i.e.*, [redacted]% of the RBA estimates exceed [redacted]%). It is reasonable to expect that future RBA estimates exceeding [redacted]% will be uncommon at similar sites of regulatory interest (*e.g.*, remedial investigation or risk assessment). Based on these considerations, the proposed value for the Absorption Fraction variable for soil and dust is estimated to be [redacted] ([redacted]%).

[redacted]

[5] The Office of Superfund Remediation and Technology Innovation has determined that a specific *in vitro* bioaccessibility (IVBA) assay for lead is a validated method for predicting RBA of lead in soils for use in site-specific human health risk assessment (U.S. EPA, 2007a,b, 2008, 2009). This IVBA assay is less expensive than and less time consuming than *in vivo* bioavailability bioassays that have been used to estimate soil lead RBA. As a result, this IVBA assay can be used to systematically characterize soil lead RBA at sites (*i.e.*, multiple samples per site) to reduce uncertainty in site-specific risk assessments and cleanup goals.

‡ The Casteel reports on site-specific bioavailability are available in the public docket for the site.

Lead in soils and dusts from small arms firing ranges had RBA values that exceeded [redacted]%) (Bannon et al., 2009). Unless site-specific RBA information is available from a validated assay, the TRW recommends a default RBA of [redacted]%) be used in cases where site history indicates that the site was a firing range.

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Table 2. Summary of Results of Swine RBA Studies

Source	TM	Lead (mg/kg soil)	Dose (μg/kg bw)	RBA [a]	Preferred Range[b]	LCL 95	UCL 95	Study Protocol	Study
Australia	Domestic incinerator	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	Single gavage dose, RBA estimated from blood AUC	Juhasz et al. 2009
		[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	Single gavage dose, RBA estimated from blood AUC	Juhasz et al. 2009
		[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	Single gavage dose, RBA estimated from blood AUC	Juhasz et al. 2009
Australia	Urban residential	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	Single gavage dose, RBA estimated from blood AUC	Juhasz et al. 2009
		[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	Single gavage dose, RBA estimated from blood AUC	Juhasz et al. 2009
Big River Mine Tailings Site, Desloge, MO	Mine tailings (TM1)	[redacted]	[redacted]	[redacted]	[redacted]			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 2006b; Results presented in Section 4.4.2 of RA
	Residential yard (TM2)	[redacted]	[redacted]	[redacted]	[redacted]			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 2006b; Results presented in Section 4.4.2 of RA
California Gulch NPL Site, Leadville, CO	AV slag	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		[redacted]	[redacted]	[redacted]	[redacted]			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1998b
California Gulch NPL Site, Leadville, CO	FeMn PbO	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		[redacted]	[redacted]	[redacted]	[redacted]			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1998b
California Gulch NPL Site, Leadville, CO	Oregon Gulch tailings	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		[redacted]	[redacted]	[redacted]	[redacted]			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1998b
California Gulch NPL Site, Leadville, CO	Phase I, residential	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		[redacted]	[redacted]	[redacted]	[redacted]			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1998b
Germany, Bruchsal	Home garden	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	28-day repeated dosing, RBA estimated from tissue Pb	Marschner et al. 2006
Germany, Carl-1	Coal mine	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	28-day repeated dosing, RBA estimated from tissue Pb	Marschner et al. 2006
Germany, Hamburg	River deposit	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	28-day repeated dosing, RBA estimated from tissue Pb	Marschner et al. 2006

Table 2. Summary of Results of Swine RBA Studies

Source	TM	Lead (mg/kg soil)	Dose (µg/kg bw)	RBA [a]	Preferred Range[b]	LCL 95	UCL 95	Study Protocol	Study
Germany, Lothringen-1	Coal mine	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	28-day repeated dosing, RBA estimated from tissue Pb	Marschner et al. 2006
Germany, Oker-11	Floodplain, playground	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	28-day repeated dosing, RBA estimated from tissue Pb	Marschner et al. 2006
Herculaneum Lead Smelter, Herculaneum, MO	HER-3201 soil	[redacted]	[redacted]	[redacted]	[redacted]			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 2006c
	Soil			[redacted] (soil) [redacted] (dust)					Section 3.5.2 of RA
Jasper County, MO Superfund Site	High level mill	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		[redacted]	[redacted]	[redacted]	[redacted]			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1996d
Jasper County, MO Superfund Site	High level smelter	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		[redacted]	[redacted]	[redacted]	[redacted]			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1996b
Jasper County, MO Superfund Site	Low level yard	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		[redacted]	[redacted]	[redacted]	[redacted]			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1996b
Kennecott NPL Site, Salt Lake City, UT	Bingham Creek, channel soil	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		[redacted]	[redacted]	[redacted]	[redacted]			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1997b
Kennecott NPL Site, Salt Lake City, UT	Bingham Creek, residential	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		[redacted]	[redacted]	[redacted]	[redacted]			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1997b; Bioavailability study documented in separate report: US EPA 1997.
Midvale Slag NPL Site, Midvale, UT	OU 2 (water quenched slag)	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		[redacted]	[redacted]	[redacted]	[redacted]			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1998c; Bioavailability study documented in

Table 2. Summary of Results of Swine RBA Studies

Source	TM	Lead (mg/kg soil)	Dose (µg/kg bw)	RBA [a]	Preferred Range[b]	LCL 95	UCL 95	Study Protocol	Study
									separate report: US EPA 1998.
Murray Smelter Superfund Site, Murray City, UT	Slag	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		[redacted]	[redacted]	[redacted]	[redacted]			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1996c
Murray Smelter Superfund Site, Murray City, UT	Soil	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		[redacted]	[redacted]	[redacted]	[redacted]			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1996c; Bioavailability study documented in separate report: US EPA, 1996.
NA[c]	Galena-Enriched Soil	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		[redacted]	[redacted]	[redacted]				15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1998d
NA[d]	NIST Paint	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
New Jersey Zinc NPL, Palmerton, PA	Location 2	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		[redacted]	[redacted]	[redacted]	[redacted]			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1996d
		[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
New Jersey Zinc NPL, Palmerton, PA	Location 4	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		[redacted]	[redacted]	[redacted]	[redacted]			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1996d
Omaha Superfund Site, Omaha, NE	(TM2)	[redacted]	[redacted]	[redacted]	[redacted]			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 2004
				[redacted]				15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Results presented in Appendix B and Table 4-3 of RA. RBA values based on re-analysis, original analysis resulted in RBA values of [redacted] and [redacted]

Table 2. Summary of Results of Swine RBA Studies

Source	TM	Lead (mg/kg soil)	Dose (µg/kg bw)	RBA [a]	Preferred Range[b]	LCL 95	UCL 95	Study Protocol	Study
Omaha Superfund Site, Omaha, NE	TM1	[redacted]	[redacted]	[redacted]	[redacted]			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 2004
				[redacted]				15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Results presented in Appendix B and Table 4-3 of RA. RBA values based on re-analysis, original analysis resulted in RBA values of [redacted] and [redacted]
Silver Bow Creek/Butte Area NPL Site, Butte, MT	Soil	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		[redacted]	[redacted]	[redacted]	[redacted]			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1998a
Small arms range, AK	Soil	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Bannon et al. 2009
Small arms range, LA	Soil	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Bannon et al. 2009
Small arms range, MD	Soil	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Bannon et al. 2009
Small arms range, MD	Soil	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Bannon et al. 2009
Small arms range, NE	Soil	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Bannon et al. 2009
Small arms range, OR	soil	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Bannon et al. 2009
Small arms range, SD	Soil	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Bannon et al. 2009
Small arms range, WA	Soil	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Bannon et al. 2009
Smuggler Mountain NPL Site, Aspen, CO	Aspen berm	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		[redacted]	[redacted]	[redacted]	[redacted]			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1996a
Smuggler Mountain NPL Site, Aspen, CO	Residential composite	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]	15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al. 2006a
		[redacted]	[redacted]	[redacted]	[redacted]			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 1996a

Table 2. Summary of Results of Swine RBA Studies

Source	TM	Lead (mg/kg soil)	Dose (µg/kg bw)	RBA [a]	Preferred Range[b]	LCL 95	UCL 95	Study Protocol	Study
Tacoma, WA	Soil	[redacted]	[redacted]	[redacted]		NA	NA	30-day in diet, RBA estimated from tissue Pb	Smith et al. 2009
Vasquez Boulevard/I-70 Site (VB-I70), Denver, CO	Eastern sample (TM1)	[redacted]	[redacted]	[redacted]	[redacted]			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 2001; Bioavailability study documented in separate report: EPA. 2001.
	Western sample (TM2)	[redacted]	[redacted]	[redacted]	[redacted]			15-day repeated dosing, multi-dose levels, RBA estimated from blood and tissue Pb	Casteel et al., 2001; Bioavailability study documented in separate report: EPA. 2001

AK: Arkansas; CO: Colorado; LA: Louisiana; MD: Maryland; MO: Missouri; MT: Montana; NE: Nebraska; OR: Oregon; PA: Pennsylvania; SD: South Dakota; UT: Utah; WA: Washington; OU-2: Operable Unit-2; NA: not available; TM: test material; NPL: National Priorities List; LCL: [redacted]% lower confidence limit; UCL: [redacted]% upper confidence limit.

[a]Values reported herein are as reported by the cited report, and may differ from other reports.
[b] Preferred Range refers to the interval from the RBA based on blood to the mean of the blood RBA and tissue mean RBA. The suggested point estimate (RBA) is the mid-point of the preferred range.
[c]A mixture of approximately [redacted]% NIST SRM [redacted] and [redacted]% low-Pb soil ([redacted] mg/kg) collected in Leadville, Colorado (Casteel et al., 2006a).
[d]A mixture of approximately [redacted] galena and [redacted]% low-Pb soil ([redacted] mg/kg) collected in Leadville, Colorado (Casteel et al., 2006a).
[e]Doses were estimated from plots in Figure A of Bannon et al. (2009).

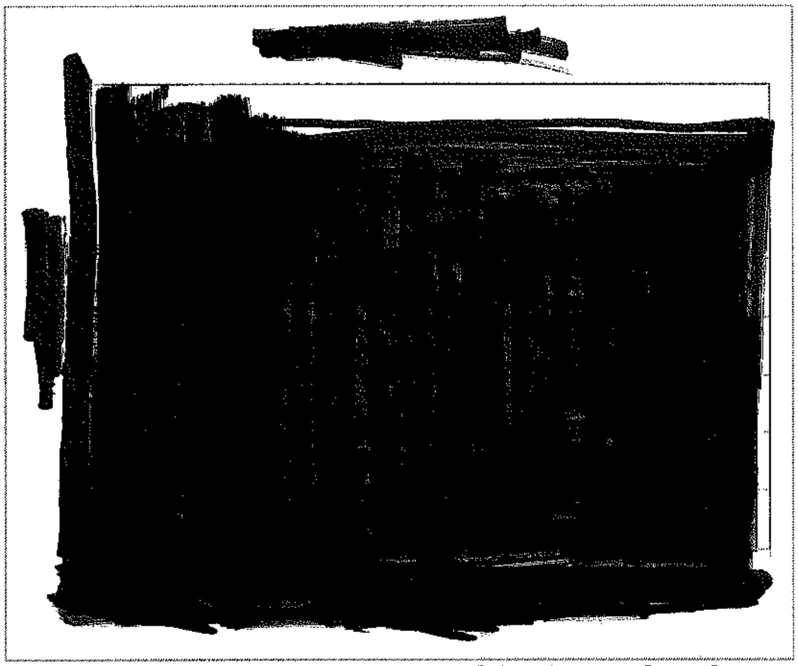

Figure 2. Distribution of test material (TM) RBAs based on swine assays. Shown are soil TMs (n=[redacted]) excluding galena-enriched soil (n=[redacted]; Casteel et al., 2006a), the NIST SRM paint sample (n=[redacted]; Casteel et al., 2006a), soil from firing range (n=[redacted]; Bannon et al., 2009), soils sieved at [redacted] mm (n=[redacted]; Marschner et al., 2006), and one interior dust sample from the Herculaneum site.

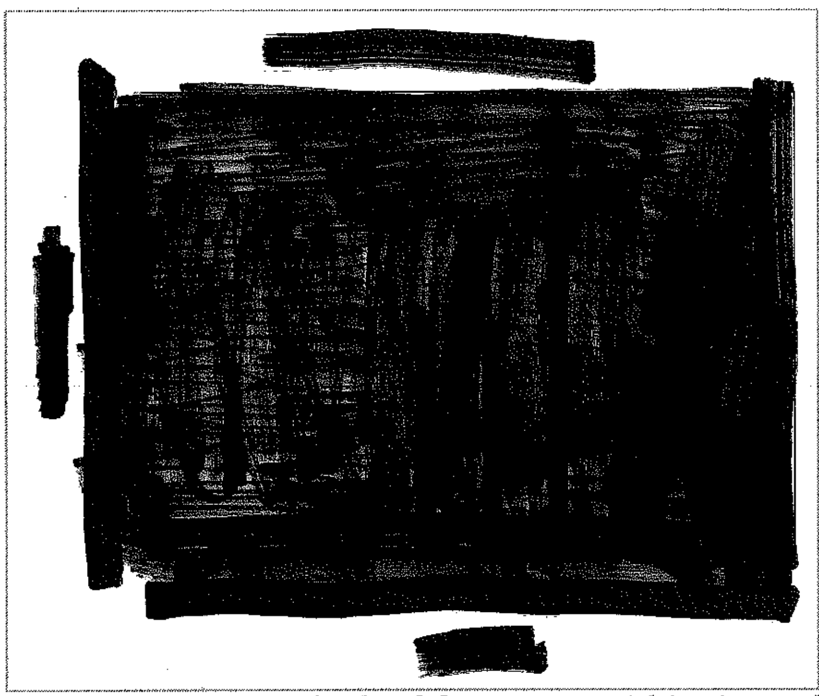

Figure 3. Distribution of soil and dust test material (TM) RBAs based on IVBA from soil (n=[redacted] from [redacted] sites) and dust (n=[redacted] from [redacted] sites) data in Table 4.

Table 3. Summary statistics of RBA estimates. The median value was used instead of the mean, because it is a more relevant statistic for this data set

Sample	Median RBA	5% – 95% Range	N (Samples/Sites)
Swine Assays			
All test materials (TMs)	[redacted]	[redacted]	[redacted]
All soil TMs[a]	[redacted]	[redacted]	[redacted]
All soil TMs[b]	[redacted]	[redacted]	[redacted]
IVBA Assays			
All soil TMs[a]	[redacted]	[redacted]	[redacted]
All soil sites	[redacted]	[redacted]	[redacted]
Dust TMs	[redacted]	[redacted]	[redacted]
Combined Swine and IVBA Assays			
All soil sites (excluding firing ranges)[b]	[redacted]	[redacted]	[redacted]

[a]Excludes galena (n=[redacted]), NIST paint (n=[redacted]), Herculaneum dust (n=[redacted], and 1 mm sieved samples (n=[redacted].
[b]Excludes small arms firing ranges (n=[redacted], galena (n=[redacted], NIST paint (n=[redacted], 1 mm sieved samples (n=[redacted] and an interior dust sample from the Herculaneum site (n=[redacted].

Table 4. Summary statistics for test material (TM) RBAs based on swine assays

	RBA	Soil RBA	Soil RBA
Parameter	**All TMs**	**All Soil TMs[a]**	**Firing Ranges Excluded[b]**
N	[redacted]	[redacted]	[redacted]
Number of sites	[redacted]	[redacted]	[redacted]
Mean	[redacted]	[redacted]	[redacted]
SD	[redacted]	[redacted]	[redacted]
[redacted]%	[redacted]	[redacted]	[redacted]
[redacted]%	[redacted]	[redacted]	[redacted]
[redacted]%	[redacted]	[redacted]	[redacted]
[redacted]%	[redacted]	[redacted]	[redacted]
[redacted]%	[redacted]	[redacted]	[redacted]

Mean, arithmetic mean; N, number of TMs; SD, standard deviation; %, percentile
[a]Excludes galena (n=[redacted], NIST paint (n=[redacted], Herculaneum dust (n=[redacted], and [redacted] mm sieved samples (n=[redacted].
[b]Excludes small arms firing ranges (n=[redacted], galena (n=[redacted], NIST paint (n=[redacted], [redacted] mm sieved samples (n=[redacted] and an interior dust sample from the Herculaneum site (n=[redacted]. Mean RBA for small arms firing ranges was [redacted]% (±[redacted]% SD).

Table 5. Summary statistics for test material (TM) RBAs based on IVBA

Parameter	Soil RBA All TMs	Dust RBA All TMs
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]%	[redacted]	[redacted]
[redacted]%	[redacted]	[redacted]
[redacted]%	[redacted]	[redacted]
[redacted]%	[redacted]	[redacted]
[redacted]%	[redacted]	[redacted]

Mean: arithmetic mean; N: number of TMs; SD: standard deviation; %: percentile

Table 6. Summary statistics of site mean RBAs based on IVBA

Parameter	Soil RBA (All Sites) [a]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]%	[redacted]
[redacted]%	[redacted]
[redacted]%	[redacted]
[redacted]%	[redacted]
[redacted]%	[redacted]

Mean: arithmetic mean; N: number of test materials (TMs); SD: standard deviation; SE: standard error; %: percentile
[a]Each site represented by the mean RBA for all soil TMs at the site.

Table 7. Summary statistics of individual site RBAs based on IVBA[a]

Site	N	Mean	SD	CV	[redacted]%	[redacted]%	[redacted]%	[redacted]%	[redacted]%
Barker-Hughesville	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Big River Mine Tailings	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
East Helena	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Eureka Mills	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Herculanuem	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
VBI70	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Madison County	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Omaha	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Pittsburg Zinc	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
St. Joe State Park	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Washington County	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

CV: coefficient of variation; Mean: arithmetic mean; N: number of test materials (TMs); SD: standard deviation; %: percentile
[a]Values presented were rounded in Microsoft Excel after the calculations were performed.

Table 8. Comparison of summary statistics for site soil and dust RBAs based on IVBA

	Herculaneum		Omaha	
Parameter	**Soil RBA**	**Dust RBA**	**Soil RBA**	**Dust RBA**
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Mean: arithmetic mean; N: number to TMs; SD: standard deviation; %: percentiles

Table 9. Effects of changing the soil and dust Absorption Fraction variable in the IEUBK model.

Absorption Fraction (%)	Lead Concentration (µg/g)		Probability Distribution		PRG for [redacted]% NTE [redacted] µg/dL
	Constant Outdoor Soil Lead	Indoor Dust Lead (MSA)	GM PbB[c] (µg/dL)	P10 (% Above)	
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

MSA: multiple source analysis; P10: probability [redacted]% of the population of exceeding [redacted] µg/dL; PRG: preliminary remediation goal; NTE: not to exceed.
[a]IEUBK model default v.1.1, build 11.
[b]Proposed IEUBK model default values.
[c]Estimated geometric mean PbB concentration (µg/dL) for children ages [redacted] months.